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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,679	HILLMAN ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-45* is/are pending in the application.

4a) Of the above claim(s) *21-23,31 and 34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30,32,33 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 21-45 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's cancellation of claims 1-20, addition of claims 21-45, and election with traverse of Group XXXI, claims 3-13 drawn to the polynucleotide of SEQ ID NO: 31 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, host cells, vectors and a method of detecting a target polynucleotide in a sample using polynucleotides, in Paper No. 8, filed on 8/1/2003 is acknowledged.

Applicants traverse the lack of unity requirement (beginning at page 8 of Paper No. 8) by stating that the unity of invention standard must be applied in national stage applications. Applicants cite sections of MPEP § 1800 in support of their statements. In response to Applicant's statements, it is noted that the unity of invention standard was applied to original claims 1-20 in evaluating the claims for unity of invention and restriction practice according to 35 U.S.C. 121 and 372. MPEP § 1893.03(d) states, "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted". As stated in the Office action of Paper No. 7, the inventions of original claims 1-20 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. See the Office action of Paper No. 7 for reasons why the inventions of original claims 1-20 lack unity of invention. In accordance with MPEP § 1893.03(d), the examiner properly applied the unity of invention standard to original claims 1-20 in the instant application.

In page 9 of Paper No. 8, applicants cite Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, which states:

Example 17

> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants argue the Examiner should withdraw the lack of unity requirement with respect to claims drawn to polypeptides comprising the sequence of SEQ ID NO: 2 (newly added claims 21-23) and claims drawn to polynucleotides which encode such polypeptides (newly added claims 24-30, 32-36, 43-45) and conclude that at least claims 21-30 and 32-45 should be examined together in a single application, in view of Example 17. Applicant's argument is not found persuasive. According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The polynucleotide of claim 33, which is drawn to an isolated polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO:31, encompasses polynucleotides that, when expressed, results in the production of proteins that do not correspond to the polypeptide of SEQ ID NO: 2. Therefore, the polynucleotide of Group XXXI, particularly the polynucleotide of claim 33, does not share a corresponding special technical feature with the polypeptide of Group II, and thus the inventions do not have unity of invention. Furthermore, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions of Groups II and XXXI do not have unity of invention because the technical feature of Groups II and XXX do not contribute over the prior art. The technical feature of Group II is a polypeptide, which is shown by Sigma Chemical Company 1997 Catalog to lack novelty or inventive step because Sigma Chemical Company 1997 Catalog teaches a Gly-Gln bioactive peptide (page 1159), corresponding to amino acids 13 and 14 of SEQ ID NO:2 that is a biologically active fragment of SEQ ID NO:2 and does not make it a contribution over the prior art. Also, the technical feature of Group XXXI is a polynucleotide, which is shown by Database GenBank Accession Number AC004241 (GI 3108007) to lack novelty or inventive step because Database GenBank Accession Number AC004241 teaches a

polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO:31 (see attached sequence alignment) and does not make it a contribution over the prior art.

In page 9 of Paper No. 8, Applicants cite sections of MPEP § 1800 and argues that newly added claims 21-45 have unity of invention because the claimed polypeptide sequences and polynucleotide sequences are corresponding technical features which are common to all of Applicant's claims and serve to technically interrelate all of Applicant's claims. Furthermore, Applicants argue that these technical features define a contribution over the prior art and that the antibody of claim 31 is technically interrelated to the polypeptide since the antibody claim recites an antibody which specifically binds to the polypeptide of SEQ ID NO: 2. These arguments are not found persuasive in view of the fact that (1) Groups II and XXXI do not share a corresponding technical feature as indicated above, and (2) the technical features of Groups II and XXXI as indicated above are not a contribution over the prior art, therefore there is no unity of invention between Group II and XXXI. As such, claims to antibodies which bind to the polypeptides of Group II do not have unity of invention with the claims of Groups II and XXXI.

Furthermore, 37 CFR § 1.475(d) does not provide for the inclusion of multiple methods of use within the main invention. As claim 30 is the first claimed method of using the polynucleotide of Group XXXI, these claims will be included and co-examined with the claims of Group XXXI. However, the additional methods of use of the polynucleotide of Group XXXI and methods of using the polypeptide of Group II do not have unity of invention in accordance with PCT Rule 13.2 and 37 CFR § 1.475(d). Therefore, the polynucleotide of Group XXXI, the polypeptide of Group II, the antibody of claim 31, additional methods of using the polynucleotide of Group XXXI, and methods of using the polypeptide of Group II do not have unity of invention. It is noted that in the original claim groupings of Paper No. 7 the examiner included claim 7, drawn to a method for detecting a target polynucleotide, as the first claimed method of using the polynucleotide of Group XXXI. However, due to applicant's re-ordering of claims in

the amendment of Paper No. 8, claim 31, drawn to a method of producing a polypeptide using a host cell comprising a recombinant polynucleotide, is now the first claimed method of using the polynucleotide of Group XXXI and will be co-examined in accordance with 37 CFR § 1.475(d).

In page 10 of Paper No. 8, Applicants argue there is minimal additional burden to examine Groups II, XXXI and LX. Applicants submit that new claims 24-30, 32-36 and 43-45 are drawn to the subject matter of Group XXXI. Applicants argue the search for the subject matter of Groups II, XXXI and LX should substantially overlap with the examination of the polynucleotide of Group XXXI since information in regard to the polynucleotide should provide information in regard to the corresponding polypeptide and antibodies. Applicant's argument is not found persuasive. As indicated above, the additional methods of use of the polynucleotides of Group XXXI are not deemed to have unity of invention in accordance with PCT Rule 13.2 and 37 CFR § 1.475(d) for the reasons set forth above. As such, claims 34-36 and 43-44 are withdrawn from consideration. In regard to the burden of search, it is noted that a comprehensive search of all Groups would require different sequence searches, patented and non-patented literature searches, as well as different class/subclass searches which would impose an undue burden on the Office. Furthermore, as stated above, 37 CFR § 1.475(d) does not provide for the inclusion of multiple methods of use within the main invention.

The requirement is deemed proper and therefore is made FINAL.

In view of Applicant's cancellation of claims 1-20, newly added claims 24-30, 32-33 and 45 will be examined since they are directed to the elected invention, i.e. polynucleotides encoding the polypeptide of SEQ ID NO: 2, host cells, vectors and the first method of use as disclosed in the newly added claims, i.e. method of recombinantly producing the polypeptide using the polynucleotide. Claims 21-23, 31, 34-44 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/109,592 filed on 11/23/1998, 60/118,610 filed on 02/04/1999, and 60/127,990 filed on 04/06/1999.

2. The instant application is the national stage of PCT/US99/28013 filed on 11/23/1999.

3. It is noted that the polypeptide of SEQ ID NO: 2 and the polynucleotide of SEQ ID NO: 31 were first disclosed in provisional application No. 60/109,592 filed on 11/23/1998.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 8/1/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

5. Claims 24-26 are objected to because they depend upon non-elected claims, i.e. claims 21-23. It is suggested that the claims be rewritten to incorporate those limitations recited in the non-elected claims. For examination purposes, the claims will be interpreted as having the limitations recited in the non-elected claims. Appropriate correction is required.

6. Claims 27-30, 33 and 45 are objected to because of the recitation of "a....polynucleotide of claim...". For clarity, it is suggested that the term be replaced with "the...polynucleotide of claim...." since the polynucleotide has already being defined as that of the corresponding claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 24, 28-30, 32-33 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 24 (claims 28-30 dependent thereon) is indefinite in the recitation in claim 21 of "a biologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 2" because it renders the claim vague and confusing. The specification discloses that the term "biologically active" refers to a protein having structural, regulatory or biochemical functions of a naturally occurring molecule. This definition, however is unclear since it does not define the biological activity associated with the term. The term "biologically active" can have many different interpretations to one of skill in the art. For example, one interpretation of the term "biologically active" in regard to polypeptides is the ability to elicit antibodies. It is suggested that the term "biologically active" be replaced with a term that clearly defines Applicant's intended biological function. For examination purposes, the term will be interpreted as "any fragment". Correction is required.

10. Claim 32 (claims 33 and 45 dependent thereon) is indefinite in the recitation of "a polynucleotide complementary to a polynucleotide of..." because it is unclear which complementary polynucleotides are encompassed by the claims. While the specification discloses that "complementarity" between two nucleic acid strands can be partial (some nucleotides will bind) or complete (all nucleotides will bind), Applicants have not define the term "complement" as it relates to size. Fragments of any size which are complementary to the polynucleotides claimed can be considered as "complements". If applicants wish to claim the entire complementary polynucleotide, wherein the all nucleotides will bind, it is suggested

that the term be replaced with "polynucleotide completely complementary to..., wherein said polynucleotide is of the same length as of ..." or similar. For examination purposes, the suggested language will be used. Correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 24-30, 32-33 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

Claims 24-30, 32-33 and 45 are directed to (1) polynucleotides encoding the polypeptide of SEQ ID NO: 2, including the polynucleotide of SEQ ID NO: 31, (2) polynucleotides comprising fragments of (1) and structural homologs thereof, (3) arrays comprising fragments of (1) or (2), (4) host cells and (5) a method to recombinantly produce the polypeptide of SEQ ID NO: 2, structural homologs, and fragments thereof.

The specification asserts that the polypeptide of SEQ ID NO: 2 is a GTPase associated protein (page 5, lines 14-19) and Table 3 discloses that the polynucleotide of SEQ ID NO: 31 is associated with cell proliferation, inflammation, and neurological conditions/diseases, these asserted utilities are not considered specific and substantial or well established for the following reasons. While Table 2 discloses that the closest homolog is a rat cAMP-regulated guanine nucleotide exchange factor (GI|4079657), and thus the specification could be interpreted to assert that the polypeptide of SEQ ID NO: 2 is a cAMP-regulated guanine nucleotide exchange factor, the specification fails to disclose which protein is associated with the exchange factor, i.e. target protein, the biological process/pathways in which this exchange factor is involved, or the specific diseases/conditions associated with the expression, or lack

thereof, of a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Since (1) no biological function is known in regard to the polypeptide of SEQ ID NO: 2, (2) no information has been provided as to whether the diseases or conditions indicated in Table 3 are associated with expression or lack of expression of the polynucleotide of SEQ ID NO: 31, (3) no disclosure has been made in regard to the specific neurological disease/conditions associated with the polypeptide of SEQ ID NO: 2, and (4) there is no indication as to the specific cell proliferation or inflammation diseases associated with the polypeptide of SEQ ID NO: 2, further research would be required to identify or reasonably confirm a real world context of use. See e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The instant situation is analogous to the lack of substantial utility examples provided by MPEP § 2107.01 in that basic research is required to study the properties of the claimed polynucleotides and the corresponding polypeptide as well as the mechanisms in which the claimed polynucleotides are involved. Also, while the specification discloses that the claimed polynucleotides can be used as probes, this use is not specific since any polynucleotide can be used as a probe. Therefore, for the reasons set forth above, one cannot reasonably conclude that the claimed invention has a specific and substantial utility.

13. Claims 24-30, 32-33 and 45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 24, 26, 28-30, 32-33 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24, 26, 28, 32, 33 and 45 are directed to a genus of polynucleotides of any function (1) encoding polypeptides having at least 90% sequence identity to SEQ ID NO: 2, (2) having at least 90% structural identity to SEQ ID NO: 31, and (3) comprising at least 60 contiguous nucleotides of the polynucleotide of SEQ ID NO: 31. Claims 29 and 30 are directed to host cells comprising the genus of polynucleotides described in (1) above and a method of recombinantly producing a genus of polypeptides of any function encoded by the genus of polynucleotides of (1).

A sufficient written description of a genus requires that the specification describe the attributes and features of a sufficient number of species within the genus so that the described species are representative of the attributes and features of all members of the genus. A complete description of any species should include description of both the structure and function of the species. While the specification provides the structure of the polynucleotide of SEQ ID NO: 31 and teaches that the polynucleotide of SEQ ID NO: 31 encodes a GTPase associated protein, the specification is silent in regard to the functions of other polynucleotides comprising at least 60 contiguous nucleotides of the polynucleotide of SEQ ID NO: 31 or the function of other structural homologs of the polypeptide of SEQ ID NO: 2 or the polynucleotide of SEQ ID NO: 31. The claimed genera are highly diverse in both structural and functional features. In addition, the genus of polynucleotides comprising at least 60 nucleotides of the polynucleotide of SEQ ID NO: 31 is an structurally diverse genus in view of the fact that the structural features of the remainder of the polynucleotides is completely undefined.

While one could argue that the claimed genera of polynucleotides are adequately described since one could obtained polynucleotides of similar function by sequence comparison using the polynucleotide

structures described in the specification and the prior art, the state of the art teaches that sequence comparison alone should not be used to determine function and that small structural changes can drastically change function. Bork teaches that protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Broun et al. teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. The art, as described above, clearly teaches that a genus of polynucleotides, as the one claimed, can potentially have many different functions which cannot be inferred by structural homology alone. The specification only discloses a single species of the genera which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the claimed genus. Thus, one skilled in the art cannot reasonably conclude that applicants had possession of the claimed invention at the time the instant application was filed.

16. Even if specific and substantial utility or well established utility is found for the polynucleotide of SEQ ID NO: 31 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, the following rejection applies. Claims 24, 26, 28-30, 32-33 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides of any function (1) encoding polypeptides having at least 90% structural identity to SEQ ID NO: 2, (2) having at least 90% structural identity to SEQ ID NO: 31, or (3) comprising at least 60 contiguous nucleotides of SEQ ID NO: 31. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims as described above is not commensurate with the enablement provided in regard to the large number of polynucleotides of unknown function encompassed by the claims as well as the infinite number of polynucleotides of unknown function comprising at least 60 contiguous nucleotides of SEQ ID NO: 31 for which no additional structure has been provided.

While the structure of the polynucleotide of SEQ ID NO: 31 is disclosed and a function has been provided for the polypeptide of SEQ ID NO: 2, the specification fails to disclose (1) other functions for all polynucleotides comprising at least 60 contiguous nucleotides of the polynucleotide of SEQ ID NO: 31, (2) critical structural elements required in a polynucleotide comprising at least 60 nucleotides of the polynucleotide of SEQ ID NO: 31 to encode a protein with the only function disclosed in the specification, i.e. GTPase associated protein, (3) which 60 contiguous nucleotides of the polynucleotide of SEQ ID NO: 31 are required in a polynucleotide to encode a polypeptide having the desired activity, (4) which structural elements can be modified in the polynucleotide of SEQ ID NO: 31 or the polypeptide of SEQ ID NO: 2 to obtain a 90% structural homolog and still encode a GTPase associated protein, or (5) examples of other polynucleotides as encompassed by the claims with the exception of the polynucleotide of SEQ ID NO: 31.

The argument can be made that the claimed invention is enabled by the teachings of the specification and what is known in the prior art since one could obtained polynucleotides of similar function by sequence comparison using the structures disclosed in the specification and those of the prior art. However, as previously discussed, the state of the art teaches the unpredictability of properly

assigning function based on structural homology. See the teachings of Bork , Van de Loo et al. and Broun et al. already discussed. The art, as described above, clearly teaches that small structural changes can result in a polypeptide having different function, therefore the claimed polynucleotides can potentially encode proteins of many different functions which cannot be inferred by structural homology alone. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to encode a GTPase associated protein, and the unpredictability of the art in regard to assigning function based on structural homology, one of skill in the art would have to go through the burden of undue experimentation in order to (1) screen and isolate the extremely large number of polynucleotides encompassed by the claims to determine which encode GTPase associated proteins, (2) determine the function of a potentially extremely large number of polynucleotides for which no function has been disclosed, and (3) determine how to use those polynucleotides of unknown function. Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and/or use the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. Claims 24-26 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Muzny et al. (GenBank accession number AC004241 GI3108007, May 2, 1998). Muzny et al. teaches a human polynucleotide (158784 nucleotides long) which comprises several fragments of at least 60 nucleotides of the polynucleotide of SEQ ID NO: 31. See attached alignment. The largest fragment is 1014 nucleotides long. It appears from the alignment that the polynucleotide of Muzny et al. is the corresponding genomic

DNA of the polynucleotide of SEQ ID NO: 31 since all the fragments of the polynucleotide of SEQ ID NO: 31 comprised by the polynucleotide of Muzny et al. when assembled together result in the entire polynucleotide of SEQ ID NO: 31. See attached alignment. As such, the genomic DNA of Muzny et al. would encode the polypeptide of SEQ ID NO: 2. Since claims 24-25 are directed to a polynucleotide which encodes the polypeptide of SEQ ID NO: 2, claim 26 is directed in part to a polynucleotide encoding the polypeptide of SEQ ID NO: 2, i.e. encoding a polypeptide which is at least 90% sequence identical to that of SEQ ID NO: 2, and claim 33 is directed to any polynucleotide comprising at least 60 nucleotides of the polynucleotide of SEQ ID NO: 31, the polynucleotide of Muzny et al. anticipates the claims as written.

Conclusion

18. No claim is in condition for allowance.

19. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
October 15, 2003

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP 1600